K073027

510(k) CLINICAL TRIAL SUMMARY

Device Trade Name: Spectra™ MRSA

Intended Use: Remel Spectra™ MRSA is a selective and differential chromogenic medium recommended for use in the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcocus aureus* (MRSA) to aid in the prevention and control of MRSA in healthcare settings. The test is performed with anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. Spectra™ MRSA is not intended to diagnose MRSA infection or to guide or monitor treatment for infections.

Device Description: Remel Spectra™ MRSA is an opaque medium, which uses a novel chromogen that yields a denim-blue color as a result of phosphatase activity. This enzyme is present in all MRSA. To allow the medium to differentiate MRSA accurately, it contains a combination of antibacterial compounds designed to inhibit the growth of a wide variety of competitor organisms. Also included are compounds that encourage the production of MRSA pathogenicity marker, ensuring expression of the phosphatase enzyme and so providing enhanced sensitivity and specificity.

Summary of Performance Data:

Clinical Accuracy:
The performance of Spectra™ MRSA was evaluated at four geographically diverse regions of the United States. A total of seven hundred sixty-seven (767) prospective anterior nare surveillance specimens were tested. Results from the Spectra™ MRSA at 24 hours incubation were compared to results obtained from traditional culture on Tryptic Soy Agar with 5% Sheep Blood (Blood Agar) after 48 hours incubation. During the course of this study, one swab was used to inoculate both plates, with the Blood Agar plate being inoculated first for all specimens. The overall recovery of MRSA on Spectra™ MRSA at 24 hours was 95.4% (104/109) compared to recovery of 96.3% (105/109) on Blood Agar at 48 hours.

Suspect isolates of *S. aureus* were identified using a latex agglutination test or a biochemical identification system. Susceptibility testing was performed using an antibiotic gradient method for oxacillin and the Oxoid PBP2' test for the detection of the penicillin-binding protein 2a. The overall agreement for detection of MRSA and non-MRSA by denim blue colonies isolated on Spectra™ MRSA at 24 hours compared to identification and susceptibility testing as described was 99.1% (760/767). The positive and negative predictive values for Spectra™ MRSA compared to the Oxoid PBP2' test were 98.1% and 99.2% respectively.

		Traditional Culture	
		+	-
Spectra™ MRSA	+	100	6*
	-	5	656
TOTAL		105	662

% Agreement
MRSA: 95.2% (95% CI = 89.2–98.4%)
Non-MRSA: 99.1% (95% CI = 98.0–99.7%)
Overall: 98.6% (95% CI = 97.5–99.3%)

*Four MRSA positive specimens were negative by traditional culture at 48 hours.
Note : CI = Confidence Interval

		Oxacillin MIC	
		+	-
Spectra™ MRSA	+	104	2
	-	5	656
TOTAL		109	658

% Agreement
MRSA: 95.4% (95% CI = 89.6–98.5%)
Non-MRSA: 99.7% (95% CI = 98.9–100%)
Overall: 99.1% (95% CI = 98.1–99.6%)

		PBP2'	
		+	-
Spectra™ MRSA	+	104	2
	-	5	656
TOTAL		109	658

Sensitivity: 95.4% (95% CI = 89.6–98.5%)
Specificity: 99.7% (95% CI = 98.9–100%)
Agreement: 99.1% (95% CI = 98.1–99.6%)
Positive Predictive Value: 98.1% (95% CI = 93.4–99.8%)
Negative Predictive Value: 99.2% (95% CI = 98.2–99.8%)

Overall Agreement:

	MRSA	Non-MRSA
Spectra™ MRSA vs. traditional culture	95.2% (100/105) (95% CI = 89.6–98.5%)	99.1% (656/662) (95% CI = 98.9–100%)
Spectra™ MRSA vs. PBP2'	95.4% (104/109) (95% CI = 89.6–98.5%)	99.7% (656/658) (95% CI = 98.9–100%)
Spectra™ MRSA vs. Oxacillin MIC	95.4% (104/109) (95% CI = 89.6–98.5%)	99.7% (656/658) (95% CI = 98.9–100%)

*Four MRSA positive specimens were negative by traditional culture at 48 hours.

Performance Compared to Commercially Available Devices:
Spectra™ MRSA was compared to traditional culture and susceptibility testing and the BD BBL™ CHROMagar™ MRSA with a total of 273 prospective nasal surveillance specimens. One swab was used to inoculate Blood Agar first and Spectra™ MRSA second. The second swab was used to inoculate the BD BBL™ CHROMagar™ MRSA. There was 98.9% agreement with traditional culture and susceptibility testing, and 97.1% agreement with the BD BBL™ CHROMagar™ MRSA. In this study, two nasal swabs were collected per patient.

Interfering Substances:
Commonly used medicinal substances and transport media, as well as human blood and mucous were evaluated for potential interference of the chromogenic reaction of Spectra™ MRSA. No interference was observed.

Reproducibility:
Reproducibility testing was conducted at four sites on three separate days with twenty blinded strains of *Staphylococcus aureus*. The strains consisted of 12 MRSA, 7 MSSA; 1 BORSA. MRSA and MSSA strains produced the expected result with Spectra™ MRSA 100% of the time at 24 hours. BORSA demonstrated variable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 28 2008

Mary Ann Silvius
Director Clinical Marketing
Remel Products
Thermo Fisher Scientific
12076 Santa Fe Drive
Lenexa, KS 66215

Re: k073027
Trade/Device Name: Remel Spectra™ MRSA
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture media, Antimicrobial susceptibility test, excluding Mueller Hinton Agar
Regulatory Class: Class II
Product Code: JSO
Dated: January 28, 2008
Received: January 30, 2008

Dear Ms. Silvius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K073027

Device Name: Spectra™ MRSA

Indications For Use: Remel Spectra™ MRSA is a selective and differential chromogenic medium recommended for use in the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcocus aureus* (MRSA) to aid in the prevention and control of MRSA in healthcare settings. The test is performed with anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. Spectra™ MRSA is not intended to diagnose MRSA infection or to guide or monitor treatment for infections.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073027